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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/088,750

03/20/2002

Nobuhiko Nakashima

3190-015

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33432

7590

04/25/2006

KILYK & BOWERSOX, P.L.L.C.

400 HOLIDAY COURT

SUITE 102

WARRENTON, VA 20186

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,750

Applicant(s)

NAKASHIMA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,12,14,16-20,22-25 and 27-31 is/are pending in the application.
4a) Of the above claim(s) 1-4,12,14,18,19,28 and 29 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 9,17,20,24,27,30 and 31 is/are rejected.
7) ☒ Claim(s) 16,22,23 and 25 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 9, 12, 14, 16-20, 22-25 and 27-31 are pending.

Applicants' amendment filed on February 22, 2006 is acknowledged. Applicants' response has been fully considered. Claims 16, 20 and 30 have been amended, and claims 13, 15 and 21 have been cancelled. Claims 1-4, 12, 14, 18, 19, 28 and 29 are non-elected inventions and withdrawn from consideration. Thus, claims 9, 16, 17, 20, 22-25, 27, 30 and 31 are examined.

This application contains claims 1-4, 12, 14, 18, 19, 28 and 29 drawn to an invention nonelected with traverse in the response to restriction requirement filed December 16, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 13, 15 and 21 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of the claims in the amendment filed February 22, 2006.
3. The previous rejection of claim 13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claim, and applicants' response at pages 12-13 in the amendment filed February 22, 2006.

Withdrawn Claim Rejections - 35 USC § 102

4. Previous rejection of claims 9, 13, 15, 16 and 20-23 under 35 U.S.C. 102(b) as being anticipated by Sasaki *et al.* (J. Virology, 73, 1219-1226 (1999)) is withdrawn in view of

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applicant's amendment of the claims, and applicants' response at pages 13-15 in the amendment filed February 22, 2006.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Previous rejection of claims 9, 17, 24, 27, 30 and 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's arguments have been fully considered, and the response to the argument is shown below.

Claims 9, 17, 24, 27, 30 and 31 are directed to a method of synthesizing a heterologous polypeptide or a method of initiating synthesis of arbitrary heterologous polypeptide *in vitro*, the method comprising utilizing a polynucleotide that promotes translation activity and has an RNA higher-order structure including PK (pseudoknot) I, II and III structures, wherein the polynucleotide that promotes translation activity is selected from: 1) one of the sequences of SEQ ID NO:1-7; 2) a base sequence containing SEQ ID NO:1-6 or 7; 3) a base sequence substantially identical to the base sequence of 1) and having the at least PK I, II and III structures or a structure homologous thereto, and wherein the polynucleotide encoding the heterologous polypeptide is immediately downstream from the PKI structure of the polynucleotide that promotes translation activity. While the specification discloses an RNA higher-order structure

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having a function of promoting translation activity contains a base sequence of SEQ ID NO:1-6 or 7 (pages 6-7); the RNA higher-order structure of SEQ ID NO:1 containing three pseudoknot structures (PK I, II and III) contributes to the initiation and acceleration of translation of a protein (e.g., luciferase) *in vitro* and a specific mutation of PK I in the PSIV-IRES permits translation of a GFP gene, where *in vitro* translation was carried out using a rabbit reticulocyte lysate (Example 1; Figs. 7 and 8); utilizing a mutated PSIV-IRES permits translating a heterologous protein that begins with an arbitrary amino acid in cell-free system using a wheat germ extract (Example 2, Fig. 9); and a base sequence substantially identical to the base sequence of SEQ ID NO:1-6 or 7 is a base sequence having a homology at least 50% to the base sequence of SEQ ID NO:1-7 and having the at least PK I, II and III structures or a structure homologous thereto (the paragraph bridges between pages 7 and 8), it does not describe a genus of variants for a polynucleotide sequence that is substantially identical to the base sequence of SEQ ID NO:1-6 or 7 and having a function for promoting translation activity, or a structure homologous to the structures of PK I, II and III in the RNA higher-order structure. For example, the specification does not identify the portion of the polynucleotide sequence identical to the base sequence of SEQ ID NO:1-7 in the sequence having at least 50% homology to the base sequence, or the nucleotides in the base sequence being modified (i.e., including deletion, substitution, addition or insertion) and still keeping the modified sequence functional; nor demonstrates any of these polynucleotide variants having translation activity. Furthermore, the specification has not described the structures that are homologous to the structures of PK I, II and III. Without guidance on structure to function/activity relationship for variants of SEQ ID NO:1-7, one skilled in the art would not know which nucleotides in the sequences of SEQ ID

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NO:1-7 are essential for its translation activity, and how to identify a functional polynucleotide from numerous polynucleotides having at least 50% homology to SEQ ID NO:1-7. The lack of description of structure to function/activity relationship for variants of SEQ ID NO:1-7 and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Argument

Applicants indicate claims 20 and 30 have been amended, and the amendment to the claims would overcome the rejection (pages 11 and 12 of the response).

Applicants' response has been considered, however, the argument is not persuasive because the specification merely describes specific higher-order RNA structures with a defined base sequence of SEQ ID NO:1-7 (Example 1, Figs. 15 and 16; pages 5-6) and a specific mutation in the PK I of PSIV-IRES (Fig. 7), and provides a general description regarding sequence homology or mutation on the base sequence of SEQ ID NO:1-7 (pages 7-8), it does not provide sufficient teachings on the identities of the functional polynucleotide variants for the sequences having at least 50% homology to SEQ ID NO:1-7 and modified sequence of SEQ ID NO:1-7. As indicated in the paragraph above, without establishing the correlation of the structure to function/activity for variants of SEQ ID NO:1-7, the functional polynucleotide variant of SEQ ID NO:1-7 cannot be readily identified. Therefore, applicants have failed to sufficiently describe the claimed invention that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Objection

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6. Claims 16, 22, 23 and 25 are objected to because the claim is dependent from a rejected claim, claim 20.

Conclusion

7. Claims 9, 17, 20, 24, 27, 30 and 31 are rejected; and claims 16, 22, 23 and 25 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

April 21, 2006